

**UNITED STATES DISTRICT COURT
DISTRICT OF NEW JERSEY**

SUCAMPO AG, SUCAMPO
PHARMACEUTICALS, INC.,
SUCAMPO PHARMA, LLC, TAKEDA
PHARMACEUTICAL COMPANY
LIMITED, TAKEDA
PHARMACEUTICALS USA, INC., and
TAKEDA PHARMACEUTICALS
AMERICA, INC.,

Plaintiffs,

v.

SUN PHARMACEUTICAL INDUSTRIES,
LTD. and SUN PHARMACEUTICAL
INDUSTRIES, INC.,

Defendants.

Civil Action No. 18-15482 (FLW)(TJB)

(Filed Electronically)

CONSENT JUDGMENT AND ORDER OF PERMANENT INJUNCTION

This action for patent infringement (the “Patent Litigation”) has been brought by Plaintiffs Sucampo AG, Sucampo Pharmaceuticals, Inc., Sucampo Pharma, LLC (collectively, (“Sucampo”), Takeda Pharmaceutical Company Limited, Takeda Pharmaceuticals USA, Inc., and Takeda Pharmaceuticals America, Inc. (collectively, “Takeda” and together with Sucampo, “Plaintiffs”) against Defendant Sun Pharmaceutical Industries, Ltd. (“Sun Ltd.”) and Sun Pharmaceutical Industries, Inc. (“Sun Inc.”) (collectively, “Sun” or “Defendants”) for infringement of United States Patent Nos. 7,795,312 (“the ’312 Patent”) , 8,026,393 (“the ’393 Patent”), 8,097,653 (“the ’653 Patent”), 8,338,639 (“the ’639 Patent”), 8,389,542 (“the ’542 Patent”), 8,748,481 (“the ’481 Patent”), and 8,779,187 (“the ’187 Patent”) (collectively, the “Sucampo Patents”). Plaintiffs’ commencement of the Patent Litigation was based on its

receipt of notice from Sun that Sun filed ANDA No. 212292 with the United States Food and Drug Administration containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) directed to the Sucampo Patents and seeking approval to market generic versions of 8 mcg and 24 mcg lubiprostone capsules.

Plaintiffs and Sun have now agreed to a good-faith final resolution regarding this Patent Litigation on the expectation and belief that this would eliminate the substantial litigation costs that would otherwise be incurred by both Plaintiffs and Sun during the Patent Litigation, while also serving the public interest by saving judicial resources and avoiding the risks to each of the parties associated with infringement. This Court shall retain jurisdiction over Plaintiffs and Sun to enforce the final resolution. Plaintiffs and Sun also believe that this resolution gives them the procompetitive opportunity to more productively use money and other resources that would have been spent in the continued prosecution and defense of this Patent Litigation, to the benefit of the parties and consumers alike, such as by investing more money in pharmaceutical research and development.

Each of Plaintiffs and Sun acknowledge there is significant risk to each of them associated with the continued prosecution of this Patent Litigation and have consented to judgment through a final resolution as reflected in the Consent Judgment set forth herein. The Court, upon the consent and request of Plaintiffs and Sun, hereby acknowledges the following Consent Judgment and, upon due consideration, issues the following Order.

Plaintiffs and Sun now consent to this Consent Judgment and Order of Permanent Injunction and

IT IS, this 2nd day of July, 2020,

HEREBY ORDERED, ADJUDGED AND DECREED that:

1. This Court has subject matter jurisdiction over this patent infringement action, and personal jurisdiction over Plaintiffs and Sun for purposes of this action. Venue is proper in this Court as to Plaintiffs and Sun as to this action.

2. In this Patent Litigation, which was filed on October 30, 2018, Plaintiffs have charged Sun with infringement of the Sucampo Patents in connection with Sun's submission of Abbreviated New Drug Application ("ANDA") No. 212292 directed to generic tablets containing 8 mcg and 24 mcg of lubiprostone per capsule ("Sun's ANDA No. 212292 Products") to the U.S. Food and Drug Administration ("FDA").

3. In response to Plaintiffs' charges of patent infringement, Sun has alleged certain defenses, including that the Sucampo Patents are invalid. No decision has been obtained by the Plaintiffs from this Court regarding these charges of infringement or these defenses.

4. Sun has not obtained a decision from the Court finding that it has rebutted the statutory presumption that the Sucampo Patents are valid and enforceable in the Patent Litigation.

5. Sun admits that the submission of ANDA No. 212292 containing a certification pursuant to 21 U.S.C. § 355(j)(2)(A)(vii)(IV) to the FDA for the purpose of obtaining regulatory approval to engage in the commercial manufacture, use and/or sale of Sun's ANDA No. 212292 Products within the United States before the expiration of the Sucampo Patents was a technical act of infringement of the Sucampo Patents under 35 U.S.C. § 271(e)(2)(A). This admission is further without prejudice to any claim, defense or counterclaim in any future action between Sun and Plaintiffs, or any successor-in-interest to

Sucampo, regarding the Sucampo Patents and/or a generic lubiprostone product other than Sun's ANDA No. 212292 Products.

6. Both parties have agreed that each of the defenses and counterclaims set forth in Sun's Answer, including the allegations and averments contained therein, should be dismissed, without prejudice.

7. Sun, its officers, agents, servants, employees and attorneys, and those persons in active concert or participation with them who receive actual notice of this Order by personal service or otherwise, are hereby enjoined from manufacturing, using, offering to sell or selling within the United States, or importing into the United States, any generic capsule product containing 8 mcg and/or 24 mcg of lubiprostone per capsule that is the subject of ANDA No. 212292 until January 1, 2023 or at such earlier date as may be permitted by the resolution to which the Parties have agreed.

8. Plaintiffs acknowledge that Sun is entitled to maintain their Paragraph IV certification to the Sucampo Patents pursuant to 21 C.F.R. § 314.94(a)(12)(v).

9. Plaintiffs and Sun each expressly waives any right to appeal or otherwise move for relief from this final Consent Judgment and Order of Permanent Injunction.

10. This Court retains jurisdiction over Plaintiffs and Sun for purposes of enforcing this final Consent Judgment and Order of Permanent Injunction.

11. This Consent Judgment and Order of Permanent Injunction is without prejudice to, and shall have no preclusive effect as to, any claim, defense or counterclaim in any future action between Sun or any successor-in-interest to Sun, and Plaintiffs, or any successor-in-interest to Plaintiffs, regarding the Sucampo Patents and/or a generic lubiprostone product other than Sun's ANDA No. 212292 Products. Further, this Consent

Judgment and Order of Permanent Injunction shall not be admissible in evidence, as an admission of Sun or otherwise, in any such future action.

12. The Clerk of the Court is directed to enter this final Consent Judgment and Order of Permanent Injunction forthwith, and thereafter close this matter.

IT IS HEREBY STIPULATED:

Dated: July 1, 2020

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SO ORDERED:

/s/ Freda L. Wolfson

THE HONORABLE FREDA L. WOLFSON
United States Chief District Judge